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- (71) Applicant (*for all designated States except US*): ETHICON GMBH [DE/DE]; Robert-Koch-Str. 1, D-22851 Norderstedt (DE). Published: — *With international search report.*
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): SCHULDT-
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(54) Title: REINFORCED AREAL IMPLANT

(57) Abstract: A reinforced areal implant particularly suitable to the repair of inguinal hernias has a net-type basic structure with a pore size of 1.5 mm to 4.0 mm and comprises textile strengthening elements, whose bending resistance, measured in a three-point flexibility test at a support length of 20 mm, is in the range 0.015 N/mm to 0.4 N/mm. The basic structure preferably contains a non-absorbable material and additionally an absorbable multifilament yarn.

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Reinforced Areal Implant

The invention concerns a reinforced areal implant, which can be used particularly for the repair of inguinal hernias.

From U.S. Patent 2 671 444, a net-type surgical implant for the treatment of hernias is known. This implant is manufactured from polyethylene and can be cut to the required size by a surgeon. One disadvantage is that the implant is relatively stiff.

In order to improve the cloth-like quality of an implant net made from polypropylene or polyester for the treatment of hernias, it is proposed in DE 295 11 411 U1 to arrange attachments to the implant net, which are at least partially absorbable and which adhere to anatomical structures.

Furthermore, there are available implant nets made of polypropylene mono-filament which have a relatively great areal weight (implant mass) of 100 g/m^2 and a pore size of less than 1 mm. These implants nets are very stiff. Therefore, they are good for a laporoscopic application, as they unfold without difficulty, for example, but they do not match anatomical conditions in an optimal way. Thus, a cavity is readily formed,

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if these implants are used for the repair of inguinal hernias. Further disadvantages are the formation of a thick, strong scar plate and a disturbance of abdominal wall movement. Moreover, it is hard to see through such implant nets, which makes operations more difficult.

Conventional implant nets knitted from a composite material having an absorbable and a non-absorbable constituent are less stiff. Warp and pillar stitch are made of multi-filament yarns from non-absorbable polypropylene and an absorbable copolymer of L-lactide and glycolide in the ratio 10:90, which is marketed by the applicant under the designation "Vicryl". The areal weight amounts to about 56 g/m^2 with a polypropylene part of about 25 g/m^2 . These implant nets fit the anatomical conditions well; they are soft and flexible and form no folds or cavities. Only a weak scar formation comes about, and the abdominal wall movement is not seriously disturbed. A pore size of about 2-4 mm provides good transparency. The reduced stiffness, however, brings disadvantages. For example, handling during care of an inguinal hernia is made more difficult. Such implant nets are ill-suited for laporoscopic use, as they are hard to unfold. In particular, a partial fold-out of the implant net against the spermatic cord can lead to problems.

The object of the invention is to provide an areal implant particularly suitable for repairing an inguinal hernia which on the one hand offers a good fit to anatomical conditions, but on

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the other hand is easily handled and can also be used for laparoscopic applications.

This problem is solved by a reinforced areal implant with the features of Claim 1. Advantageous versions of the invention emerge from the sub-claims.

The reinforced areal implant according to the invention has a net-type basic structure with a pore size in the range 1.5 mm to 4.0 mm. It comprises textile strengthening elements whose bending resistance is in the range 0.015 N/mm to 0.4 N/mm. The bending resistance is given here with numerical values which can be determined in a three-point flexibility test in which the bending in the middle of a textile strengthening element is measured as a function of the force acting onto the middle of the textile strengthening element and perpendicularly to the textile strengthening element, where the (free) support length of the textile strengthening element is 20 mm. The numerical value given for the bending resistance in N/mm arises from the slope of this experimental curve in the region of smaller forces or bendings, where largely linear conditions dominate.

The net-type basic structure, at a pore size of 1.5 mm to 4.0 mm, is relatively coarse-mesh so that good transparency to the underlying tissue is possible, which facilitates surgery. The relatively large pores of the net-type basic structure also permit the entire implant mass being held low. The areal weight

of the reinforced areal implants according to the invention is preferably in the range 50 g/m^2 to 150 g/m^2 . If the implant mass is low, after the surgery there are less foreign-matter reactions, and the implant heals in well, which again is assisted by the relatively large pores. On the other hand, the pores are sufficiently small for the net-type basic structure to accomplish the required support and holding function in the area of the surgery.

The textile strengthening elements have the effect that the reinforced areal implant according to the invention, as a whole, has an adequate stiffness for handling. It can therefore be well used in inguinal hernia repairs and also in laparoscopic applications. For example, the edges of the implant do not fold out, if the implant, starting at one of its edges, is cut, in order to lay it round the spermatic cord. On the other hand, the implant is not too stiff so that it fits to the anatomical conditions without folds or cavity formation and also does not essentially disturb the movability of the abdominal wall.

Preferably, the strengthening elements form a net-type strengthening structure with a pore size from 5 mm to 30 mm, this pore size preferably being several times the pore size of the basic structure. Such a coarse-mesh arrangement of the strengthening elements is sufficient to provide a sufficient stiffness of the implant.

In a preferred embodiment, the basic structure of the implant comprises a knitted fabric. Preferably, the strengthening elements are laid or knitted into the basic structure. In this case, the implant can be produced as a whole through a mesh-forming process. A possibility is the production with the aid of the multi-bar technology on crochet galloon machines or raschel machines.

Preferably, the basic structure comprises non-absorbable material (e.g. multi-filament yarn of polypropylene) or very slowly absorbed material (i.e. material that 180 days after the surgery still has at least 50% of its initial tear-strength), e.g. in a contribution with an areal weight in the range of 10 g/m² to 50 g/m². As this material is not absorbed or only slowly absorbed, the basic structure can assume the desired supporting and holding function in the patient's body permanently or at least for a very long period of time.

It is particularly advantageous, if additionally the basic structure has absorbable multi-filament yarn. For example, yarns of poly-p-dioxanone or yarns of a copolymer of L-lactide and glycolide (especially in the ratio 10:90, i.e. "Vicryl", or in the ratio 95:5) or mixtures of such yarns or multi-filament yarns are suitable. The absorbable yarns in the basic structure have the effect that the implant fits particularly well to local anatomical conditions and shows no folds or cavity formation on application. It is particularly helpful if a relatively large

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part of "Vicryl" multi-filament yarns is used. Fine "Vicryl" yarns are very quickly moistened by body fluids and therefore adhere to soft body tissue like fascia, muscles or the peritoneum much better than fabric structures from polypropylene multi-filament yarns or mono-filaments, which are very hydrophobic. With the aid of absorbable multi-filament yarns in the basic structure, it is thus possible for the implant in the operating area to fit very well and to attach to tissue, although it is relatively stiff as a whole, so as to improve handling.

For the strengthening elements, in particular pure mono-filaments, twisted mono-filaments, twisted or composite multi-filament yarns or mixtures thereof are suitable. The strengthening elements can be non-absorbable, partly absorbable, or completely absorbable. Suitable for strengthening elements are, for example, mono-filaments of polypropylene, multi-filament yarns of polypropylene, mono-filaments of poly-p-dioxanone, multi-filament yarns of a copolymer of L-lactide and glycolide in the ratio 10:90 ("Vicryl"), yarns of poly-p-dioxanone or mixtures thereof.

In a preferred embodiment of the invention, at least part of the strengthening elements has a color different from that of the basic structure. In this way, it is possible to provide the implant with a coarse-mesh colored grid, which makes it easier to a surgeon during surgery to assess any distortion of the

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implant. Preferably the color remains temporary only, i.e. after the surgery it fades. If the strengthening elements have several components, e.g., a mono-filament part or a multi-filament part of the strengthening elements can be colored.

Preferably, an implant provided for a surgical operation will be cut to size from areal material beforehand. But it is possible to use pre-made-up implants, for which, if required, the edge region can be secured against unravelling or reinforced. For the treatment of inguinal hernias, implants can be advantageous which have an aperture for the spermatic cord.

In the following, the invention is described more precisely by means of examples. The figures show in

Figure 1 a schematic representation of the knitting pattern of a first embodiment of the reinforced areal implant according to the invention,

Figure 2 a schematic representation of the knitting pattern of a second embodiment of the reinforced areal implant according to the invention, and

Figure 3 a schematic representation of the knitting pattern of a third embodiment of the reinforced areal implant according to the invention.

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In the figures 1 to 3 the model patterns (paper notation of patterns) and mesh layout of three embodiments of reinforced areal implants are represented schematically in a way familiar to the expert. The implants according to these three embodiments have a basic structure, into which strengthening elements (model shoot III, model shoot IV) are inserted.

Table 1 Thread system and material in the three embodiments according to model I, model II und model III

No.	Thread System	Material
I	Warp: open pillar stitch	1 x 60 den PP twine
	Model shoot I+II: Basic knitting construction Rapport across 6 loops	Twist of 4 x 80 den "Vicryl" + 1 x 60 den PP
	Model shoot III+IV: Pattern structure Rapport across 24 loops	Twist variant H Twist of 4 x 60 den PP, 2 x 80 den "Vicryl", violet and 1 x 6 mil PP mono-filament 1 x 4 fold twist + mono-filament
II	Warp: open pillar stitch	1 x 60 den PP twine
	Model shoot I+II: Basic knitting construction Rapport across 6 loops	Twist of 4 x 80 den "Vicryl" + 1 x 60 den PP
	Model shoot III+IV: Pattern structure Rapport across 36 loops	Twist variant D Twist of 2 x 80 den "Vicryl", violet, and 4 x 60 den PP
III	Warp: open pillar stitch	1 x 60 den PP twine
	Model shoot I+II: Basic knitting construction Rapport across 6 loops	Twist of 4 x 80 den "Vicryl" + 1 x 60 den PP

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Model shoot III+IV:	Twist variant I
Pattern structure	Twist of 4 x 60 den PP,
Rapport across 24 loops	2 x 80 den "Vicryl", violet and
	1 x 6 mil PP mono-filament
	1 x 7 fold twist

1 mil = 0.0254 mm; 1 den = 1 Denier

Further data for the thread systems and data concerning the material and kind of the yarns and filaments used are listed in Table 1 for these three embodiments. The strengthening elements "twist variant H" (model I), "twist variant D" (model II), and "twist variant I" (model III) are explained further below in more detail. In the case of all three embodiments, both the basic structure and the strengthening elements comprise absorbable and non-absorbable material, namely polypropylen (PP) as non-absorbable material and a copolymer of L-lactide and glycolide in the ratio 10:90 ("Vicryl") as absorbable material.

There follow some embodiments of strengthening elements which can be used in a reinforced areal implant. In the examples, in a way familiar to the expert, the materials and construction of the strengthening elements as well as their diameter and bending resistance are given. The latter is measured in a three-point flexibility test at a support length of 20 mm, as explained further above.

Example A

Material: Mixture of poly(vinylidene fluoride) and poly((vinylidene fluoride)-co-hexafluoropropylene)

Structure: Mono-filament

Diameter: 0.247 mm

Bending resist.: 0.243 N/mm

Example B

Material: PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den)

Structure: 6 x 60 den PP and 2 x 80 den "Vicryl"; twist

Diameter: 0.428 mm

Bending resist.: 0.023 N/mm

Example C

Material: PP mono-filament (thickness 6 mil) and violet "Vicryl" multi-filament yarn (80 den)

Structure: 3 x 6 mil mono-filament and 2 x 80 den "Vicryl", violet

Diameter: 0.328 mm

Bending resist.: 0.147 N/mm

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Example D

Material: PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den)

Structure: 4 x 60 den PP and 2 x 80 den "Vicryl", violet

Diameter: 0.294 mm

Bending resist.: 0.017 N/mm

Example E

Material: PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den)

Structure: 6 x 60 den PP yarn and 2 x 80 den "Vicryl" yarn as two-step twist: 1st step 1254 T/m, S-twist; 2nd step 465 T/m, Z-twist

Diameter: 0.407 mm

Bending resist.: 0.031 N/mm

Example F

Material: PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den)

Structure: 6 x 60 den PP yarn and 2 x 80 den "Vicryl" yarn as two-step twist: 1st step 1769 T/m, S-twist; 2nd step 695 T/m, Z-twist

Diameter: 0.338 mm

Bending resist.: 0.021 N/mm

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Example G

Material: PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den); plus PP mono-filament yarn

Structure: 4 x 60 den PP yarn and 2 x 80 den "Vicryl" yarn and 1 x 6 mil-PP mono-filament als two-step twist: 1st step 1112 T/m, S-twist; 2nd step 413 T/m, Z-twist (1 x 7 twist)

Diameter: 0.307 mm

Bending resist.: 0.103 N/mm

Example H

Material: PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den); plus PP mono-filament yarn

Structure: 4 x 60 den PP yarn, 2 x 80 den "Vicryl" yarn, violet, and 1 x 6 mil-PP mono-filament as two-step twist: 1st step 1112 T/m, S-twist; 2nd step 413 T/m, Z-twist; yarns shrunk in multiple-wound manner (4 + 1 twist)

Diameter: 0.395 mm

Bending resist.: 0.14 N/mm

Example I

Material: PP multi-filament yarn (60 den) and violet "Vicryl" multi-filament yarn (80 den); plus PP mono-filament yarn

Structure: 4 x 60 den PP yarn, 4 x 80 den "Vicryl" yarn, violet and 1 x 6 mil-PP mono-filament as two-step twist: 1st step 1112 T/m, S-twist; 2nd step 413 T/m, Z-twist; yarns shrunk in multiple-wound manner (4 + 1 twist)

Diameter: 0.37 mm

Bending resist.: 0.1 N/mm

The abbreviation PP, as well as the name "Vicryl" were already explained earlier. 1 mil = 0.0254 mm; 1 den = 1 Denier.

Claims

1. Reinforced areal implant, comprising
 - a net-type basic structure having a pore size in the range 1.5 mm to 4.0 mm and
 - textile strengthening elements whose bending resistance, measured in a three-point flexibility test at a support length of 20 mm, is in the range 0.015 N/mm to 0.4 N/mm.
2. Implant according to claim 1, characterized in that the strengthening elements form a net-type strengthening structure with a pore size in the range 5 mm to 30 mm, said pore size being preferably a multiple of the pore size of the basic structure.
3. Implant according to claim 1 or 2, characterized in that the basic structure comprises knitware.
4. Implant according to claim 3, characterized in that the strengthening elements are laid or knitted into the basic structure.
5. Implant according to one of claims 1 to 4, characterized in that the basic structure comprises non-absorbable material or very slowly absorbable material that retains at least 50% of its initial tear-strength after 180 days in-vivo.

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6. Implant according to claim 5, characterized in that the basic structure comprises multi-filament yarn made of polypropylene.
7. Implant according to one of claims 1 to 6, characterized in that the basic structure comprises absorbable multi-filament yarn.
8. Implant according to one of claims 1 to 7, characterized in that the basic structure has at least one of the components selected from the following group: yarn of poly-p-dioxanone, yarn of a copolymer of L-lactide and glycolide in the ratio 10:90, yarn of a copolymer of L-lactide and glycolide in the ratio 95:5, yarn of a copolymer of L-lactide and glycolide in a different ratio.
9. Implant according to one of claims 1 to 8, characterized in that the strengthening elements comprise at least one of the components selected from the following group: pure mono-filaments, twisted mono-filaments, twisted multi-filament yarns, composite multi-filament yarns.
10. Implant according to claim 9, characterized in that the strengthening elements comprise at least one of the components selected from the following group: mono-filaments of polypropylene, multi-filament yarns of polypropylene, mono-filaments of poly-p-dioxanone, multi-filament yarns of

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a copolymer of L-lactide and glycolide in the ratio 10:90, yarns of poly-p-dioxanone.

11. Implant according to one of claims 1 to 10, characterized in that at least part of the strengthening elements has a color different from that of the basic structure.

Mod II

Model pattern:

Warp Bar3 Bar4 Bar5 Bar6

2	2	4	12	0
<u>0</u>	<u>6</u>	<u>0</u>	<u>8</u>	<u>4</u>
0	2	4	10	2
<u>2</u>	<u>4</u>	<u>2</u>	<u>6</u>	<u>6</u>
	0	6	6	6
	4	2	8	4
			4	8
			<u>4</u>	<u>8</u>
			6	6
			<u>2</u>	<u>10</u>
			2	10
			<u>4</u>	<u>8</u>
			0	12
			<u>4</u>	<u>8</u>
			2	10
			<u>2</u>	<u>10</u>
			6	6
			<u>4</u>	<u>8</u>
			4	8
			<u>8</u>	<u>4</u>
			6	6
			<u>6</u>	<u>6</u>
			10	2
			<u>8</u>	<u>4</u>

Warp: open pillar stitch

Bar3: model shoot I

Bar4: model shoot II

Bar5: model shoot III

Bar6: model shoot IV

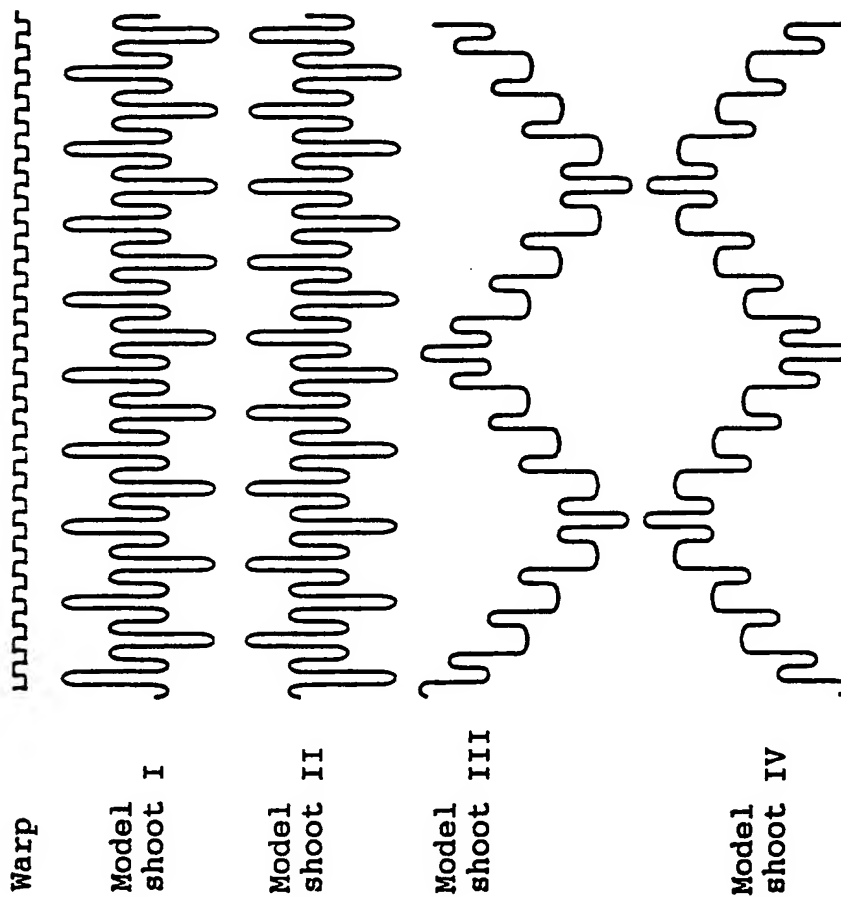


Fig. 1

Model II

Warp: open pillar stitch
 Bar3: model shoot I
 Bar4: model shoot II
 Bar5: model shoot III
 Bar6: model shoot IV

Model pattern:

Warp Bar3 Bar4 Bar5 Bar6

2	2	4	16	0
0	6	0	<u>12</u>	<u>4</u>
0	2	4	14	2
<u>2</u>	<u>4</u>	<u>2</u>	<u>10</u>	<u>6</u>
	0	6	10	6
	<u>4</u>	<u>2</u>	<u>12</u>	<u>4</u>
			8	8
			<u>8</u>	<u>8</u>
			10	6
			<u>6</u>	<u>10</u>
			6	10
			<u>8</u>	<u>8</u>
			4	12
			<u>4</u>	<u>12</u>
			6	10
			<u>2</u>	<u>14</u>
			2	14
			<u>4</u>	<u>12</u>
			0	16
			<u>4</u>	<u>12</u>
			2	14
			<u>2</u>	<u>14</u>
			6	10
			<u>4</u>	<u>12</u>
			4	12
			<u>8</u>	<u>8</u>
			6	10
			<u>6</u>	<u>10</u>
			10	6
			<u>8</u>	<u>8</u>
			<u>8</u>	<u>8</u>
			<u>12</u>	<u>4</u>
			10	6
			<u>10</u>	<u>6</u>
			14	2
			<u>12</u>	<u>4</u>

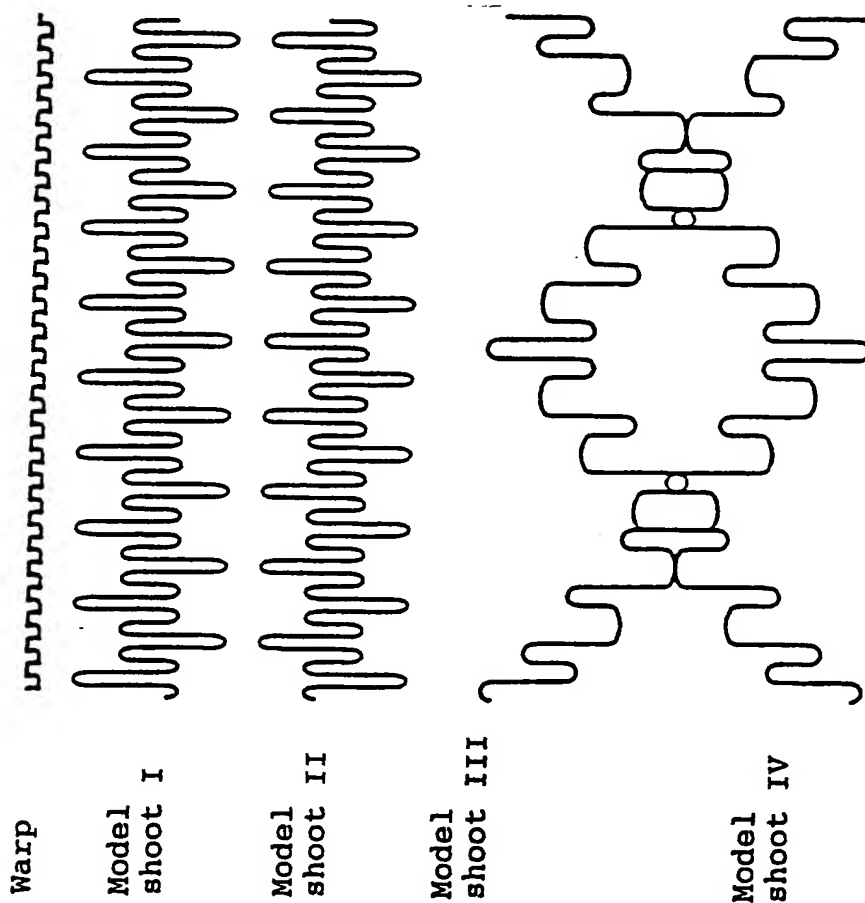


Fig. 2

Model III

Warp: open pillar stitch
 Bar3: model shoot I
 Bar4: model shoot II
 Bar5: model shoot III
 Bar6: model shoot IV

Model pattern:

Warp	Bar3	Bar4	Bar5	Bar6
2	0	4	18	0
<u>0</u>	<u>2</u>	<u>10</u>	<u>16</u>	<u>2</u>
0	0	8	18	0
<u>2</u>	<u>6</u>	<u>10</u>	<u>12</u>	<u>6</u>
	4	4	14	4
	6	6	12	6
			8	10
			<u>10</u>	<u>8</u>
			8	8
			4	4
			6	6
			4	4
			0	0
			<u>2</u>	<u>2</u>
			0	0
			6	6
			4	4
			6	6
			10	10
			8	8
			10	10
			<u>14</u>	<u>14</u>
			12	12
			<u>14</u>	<u>14</u>

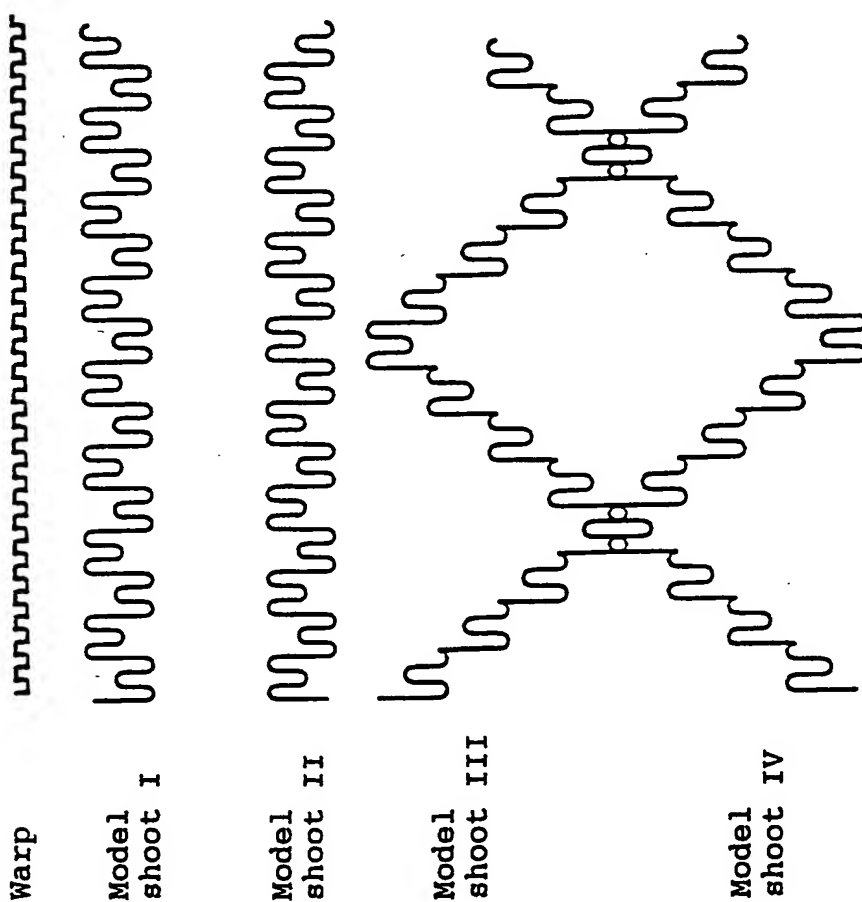


Fig. 3

INTERNATIONAL SEARCH REPORT

national application No

PCT/EP 00/04817

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 797 962 A (ETHICON GMBH) 1 October 1997 (1997-10-01) page 3, line 56 -page 6, line 12; figures 1-5 page 8, line 25 - last line; figures 10,11	1
A	FR 2 769 825 A (COGENT SARL) 23 April 1999 (1999-04-23) page 5, line 34 -page 7, line 34; figure 1	1
A	WO 96 03091 A (NOTARAS MITCHELL JAMES) 8 February 1996 (1996-02-08) page 3, line 28 -page 5, line 22; figures 1,2	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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NL - 2280 HV Rijswijk
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Information on patent family members

Patent application No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0797962	A	01-10-1997	DE 19613730 A	02-10-1997
			AU 704334 B	22-04-1999
			AU 1648597 A	02-10-1997
			BR 9701466 A	10-11-1998
			CA 2200801 A	26-09-1997
			JP 10024054 A	27-01-1998
			ZA 9702563 A	25-09-1998
FR 2769825	A	23-04-1999	AU 9453998 A	10-05-1999
			EP 1024764 A	09-08-2000
			WO 9920204 A	29-04-1999
WO 9603091	A	08-02-1996	AU 3119495 A	22-02-1996